

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Ann Marie Schmidt, et al.  
Serial No.: 09/166,649 Examiner: E. O'Hara  
Filed : October 5, 1998 Group Art Unit: 1646  
For : METHODS FOR DETERMINING WHETHER A COMPOUND IS  
CAPABLE OF INHIBITING THE INTERACTION OF A PEPTIDE  
WITH RAGE

1185 Avenue of the Americas  
New York, New York 10036  
July 24, 2003

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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JUL 29 2003

SIR:

COMMUNICATION IN RESPONSE TO JUNE 24, 2003  
NOTICE OF NON-COMPLIANT AMENDMENT

TECH CENTER 1600/2900

This Communication is submitted in response to a June 24, 2003 Notice of Non-Compliant Amendment issued by the United States Patent and Trademark Office in connection with the above-identified application. A response to the June 24, 2003 Notice of Non-Compliant Amendment is due July 24, 2003. Accordingly, this Communication is being timely filed.

The Notice, a copy of which is attached hereto as **Exhibit A**, indicates that a marked-up version of the amended claims is required in accordance with 37 C.F.R. §1.121(b)(1)(ii).

In response, applicants annex hereto as **Exhibit B** the marked-up version of the amended claims inadvertently omitted from the Amendment filed on June 10, 2003.

Applicants : Anne Marie Schmidt, et al.  
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No fee is deemed necessary in connection with the filing of this Communication. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-31.5.

<p>I hereby certify that the correspondence is being prepared in accordance with the U.S. Patent Office with sufficient regard to the requirements in an application for a patent. Commissioner of Patents, U.S. Patent Office, Washington, D.C. 20540.</p> <p><i>[Signature]</i></p> <p>Alan J. Morrison Reg. No. 37,399</p>	<p>7/24/83</p>
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May 1 1993  
Marked-up Version of the Claims

1. (Twice Amended) A method for determining whether a compound inhibits [is capable of inhibiting] the interaction of a carboxymethyl-lysine-modified advanced glycation endproduct (AGE) [peptide] with a receptor for advanced glycation end product (RAGE), which comprises:
  - (a) administering:
    - (i) the carboxymethyl-lysine-modified AGE [peptide, wherein amino groups of the peptide are inactivated by chemical derivatization],
    - (ii) RAGE or a fragment thereof which binds to the carboxymethyl-lysine-modified AGE [which is capable of binding the peptide], and
    - (iii) the compound;
  - (b) determining the amount of the AGE [peptide] bound to the RAGE or the fragment thereof; and
  - (c) comparing the amount of bound AGE [peptide] determined in step (b) with the amount determined when the AGE [peptide] is admixed with RAGE or a fragment thereof in the absence of the compound, thereby determining whether the compound inhibits the interaction of the AGE [peptide] with RAGE or fragment thereof, wherein a reduction in the amount of binding in the presence of the compound indicates that the compound inhibits the interaction.

24. (Amended) The method of claim 1, wherein the AGE [peptide] is affixed to a solid surface.

26. (Amended) The method of claim 1, wherein the AGE [peptide] is detectably labeled.



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
James C. SMITH, Director for PATENTS  
P.O. Box 4000  
Alexandria, VA 22304-4000  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/166,649	10/05/1998	ANN MARIE SCHMIDT	56613JPW/JM	9377

7590 06/24/2003  
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EXAMINER

O HARA, EILEEN B

ART UNIT

PAPER NUMBER

16-46

DATE MAILED 06/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

56613



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND  
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, DC 20530  
www.uspto.gov

1m 7.24.03

2m 8.24.03

3m 9.24.03

4m 10.24.03

5m 11.24.03

6m 12.24.03 - AP

Paper No.

## Notice of Non-Compliant Amendment (37 CFR 1.121)

The amendment filed on 6/10/03 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121, as amended on September 8, 2000 (see *65 Fed. Reg. 54603*, Sept. 8, 2000, and *1238 O.G. 77*, Sept. 19, 2000). In order for the amendment to be compliant, applicant must supply the following omissions or corrections in response to this notice.

THE FOLLOWING ITEMS ARE REQUIRED FOR COMPLIANCE WITH RULE 1.121 (APPLICANT NEED NOT RE-SUBMIT THE ENTIRE AMENDMENT):

- ☐ 1. A clean version of the replacement paragraph(s)/section(s) is required. See 37 CFR 1.121(b)(1)(ii).
- ☐ 2. A marked-up version of the replacement paragraph(s)/section(s) is required. See 37 CFR 1.121(b)(1)(iii).
- ☐ 3. A clean version of the amended claim(s) is required. See 37 CFR 1.121(c)(1)(i).
- ☒ 4. A marked-up version of the amended claim(s) is required. See 37 CFR 1.121(c)(1)(ii).

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Explanation: \_\_\_\_\_

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(LIE: Please provide specific details for correction to assist the applicant. For example, "the clean version of claim 6 is missing.")

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP §14 and the USPTO website at <http://www.uspto.gov/web/offices/dcom/olia/pbg/sampleaf.pdf>. A condensed version of a sample amendment format is attached.

- ☐ **PRELIMINARY AMENDMENT:** Unless applicant supplies the omission or correction to the preliminary amendment in compliance with revised 37 CFR 1.121 noted above within ONE MONTH of the mail date of this letter, examination on the merits may commence without entry of the originally proposed preliminary amendment. This notice is not an action under U.S.C. 132, and this ONE MONTH time limit is not extendable.
- ☒ **AMENDMENT AFTER NON-FINAL ACTION:** Since the above-mentioned reply appears to be *bona fide*, applicant is given a TIME PERIOD of ONE MONTH or THIRTY DAYS from the mailing of this notice, whichever is longer, within which to supply the omission or correction noted above in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37CFR 1.136(a).

Glenn J. Hammer  
Legal Instruments Examiner (LIE)

(Rev. 12/01)

# Changes to the Patent Rules

October 20, 2000

Volume 1, Issue 3

This is the third in a series of Patent News Bulletins to assist you in keeping up to date with significant rule changes which affect your area. Keep this copy to use as a bookmark for your present MPEP, or view this bulletin again on the USPTO Website.

## Simplified Amendment Practice.

Replacement paragraphs/sections/claims to be used. 37 CFR 1.121



*The rule package "Changes to the Patent Business Goals - Final Rule," published in the Federal Register on September 8, 2000, 65 Fed. Reg. 54603 (Sept. 8, 2000), and the Official Gazette on September 19, 2000, 1238 Off. Gaz. Pat. Office 77 (September 19, 2000). The PBG rule package makes a number of revisions to Title 37.*

*The entire final rule may be found at the USPTO Website at <http://www.uspto.gov/web/offices/dcom/ola/pbg/index.html>.*

*Areas and individuals primarily affected by this rule change include:*  
(1) Patent Examiners and Tech Support Staff in the Technology Centers  
(2) Office of Patent Publication

*Any questions related to this change in practice should be directed to Joe Narcaravage, Special Projects Exr., (703-305-1795) or Liz Dougherty, Legal Advisor, (703-306-3156) OPLA.*



Mandatory compliance with the revised rule is not required until March 1, 2001. It is suggested that applicants adopt the revised procedures on or after November 7, 2000, in order to adjust to the changes in amendment practice.

Under the new amendment practice, amendments to the specification must be made by the submission of clean new or replacement paragraph(s), section(s), specification, or claim(s). This practice will provide a specification (including claims) in clean, or substantially clean, form that can be effectively captured and converted by optical character recognition (OCR) scanning during the patent printing process.

The new practice requires applicant to provide, in addition to the clean version of a replacement paragraph/section/claim, a marked-up version using applicant's choice of a conventional marking system to indicate the changes, which will aid the examiner in identifying the changes that have been made. The marked-up version must be based on the previous version and indicate (by markings) how the previous version has been modified to produce the clean version submitted in the current amendment. The term "previous version" means the version of record in the application as originally filed or from a previously entered amendment.

The following format is suggested in an amendment paper: (1) a clean version of each replacement paragraph/section/claim with clear instructions for entry; (2) starting on a separate page, any remarks/arguments (37 CFR 1.111); and (3) starting on a separate page, a marked-up

version entitled "Version with markings to show changes made."

Applicants will also be able to submit a clean set of all pending claims, consolidating all previous versions of pending claims from a series of separate amendments into a single clean version in a single amendment paper. This submission of a clean version of all of the pending claims will be construed as directing the cancellation of all previous versions of any pending claims. No marked-up version will be required to accompany the clean version where no changes other than the consolidation are being made.

The amended rule encourages issuance of applications with an examiner's amendment without practitioners/applicants having to file a formal amendment. Additions or deletions of subject matter in the specification, including the claims, may continue to be made in an examiner's amendment at the time of allowance by instructions to make any change at a precise location in the specification or the claims. An examiner's amendment may incorporate a printed copy of a fax or e-mail amendment submitted by applicant. Only that part of the e-mail or fax directed to a clean version, or a portion of, a paragraph/claim to be added should be printed and attached to the examiner's amendment, with a paper copy of the entire e-mail or fax being entered in the file. The electronic version of the e-mail is not required to be saved once the printed e-mail (and any attachments) becomes part of the application file record.

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Amendment by  
paragraph/claim  
replacement in clean form

MPEP 714+ &amp; 1302.04